(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 192 971 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
03.04.2002 Bulletin 2002/14

(51) Int Cl.7: A61N 1/365

(21) Application number: 01120243.9

(22) Date of filing: 23.08.2001

BEST AVAILABLE COPY

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: 27.09.2000 SE 0003480

(71) Applicant: St. Jude Medical AB
175 84 Järfälla (SE)

(72) Inventor: Andersson, Jonas
121 38 Johanneshov (SE)

(54) Implantable heart stimulator

(57) An implantable heart stimulator comprises a pulse generator (3) for delivering stimulation pulses to the heart of a patient. An IEGM means (5) registers electric signals associated with the patient's heart. A classifier means (6) classifies received electric IEGM signals according to their waveforms in at least one segment of the cardiac cycle, and a control means (4) controls the pulse generator depending on the classification of the IEGM signals. A first filtering means is provided to extract parameters related to the patient's respiration from beat-to-beat variability in the IEGM signal classification while filtering away slow classification variability extending over several cardiac cycles. The control means is adapted to receive the respiration-related parameters to control the delivery of stimulation pulses from the pulse generator depending on these parameters.

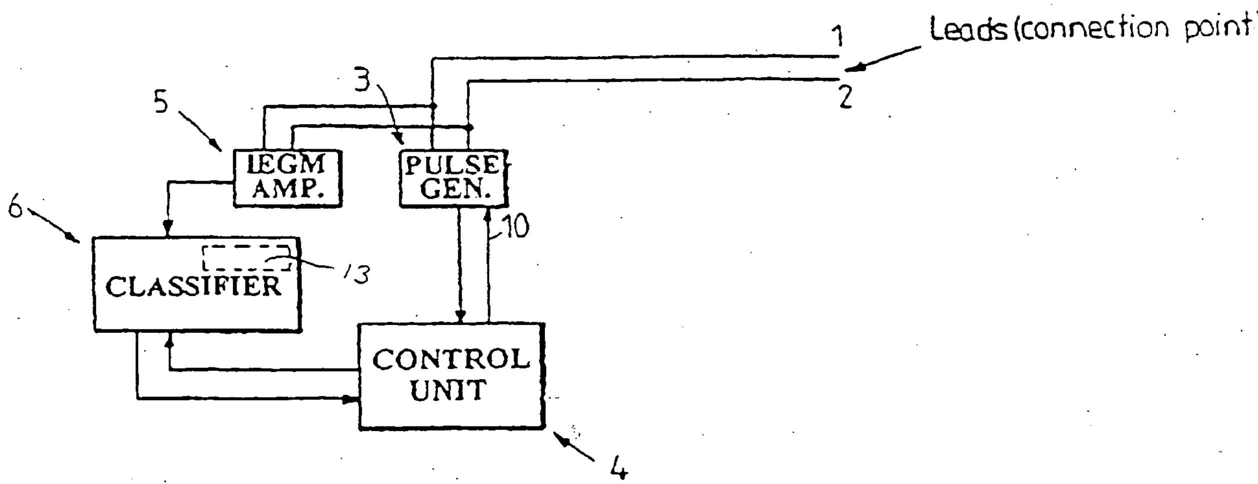

Fig. 5

EP 1 192 971 A2

Printed by Jouve, 75001 PARIS (FR)

Description

Technical field

[0001] The present invention relates to an implantable heart stimulator comprising a pulse generator for delivering stimulation pulses to the heart of a patient, an IEGM means for registering electric signals associated with the patient's heart, a classifier means for classifying the received electric IEGM signals according to their waveforms in at least one segment of the cardiac cycle, and a control means for controlling said pulse generator depending on the classification of said IEGM signals.

Background art

[0002] It is previously known to sense a physiologic parameter of a patient, classify the parameter, and use the information obtained for diagnostic purpose or for the purpose of treating the patient. Thus, US 5,645,575 describes an implantable pacemaker, which senses a general physiologic parameter of the patient for use in determining the physical stress or workload of the patient. The parameter is classified and the information obtained from this classification is used to control the stimulation rate/pulse interval of the pacemaker. The IEGM waveforms are not mentioned as the selected parameter to be sensed. US 5,215,098 and 5,280,792 describe implantable devices, which sense IEGM signals and classify them. In the device according to US 5,280,792 the classification results are used for adjusting the output of a cardioverter/defibrillator while the results of US 5,215,098 are used for diagnostic purposes only. In US 5,782,885 a method and a cardiac assist system for pacing a heart of a patient is described, in which sensed IEGM signal waveforms are classified in dependence of the workload of the patient, and the results of the classification are used to control the pulse rate or stimulation interval of a pacemaker. It is also previously known to sense IEGM signals and classify the waveforms to use the results of this classification for identifying cardiac arrhythmias and subsequent suitable therapy, see e.g. US 5,203,326, EP,A2,0 465 241 and EP,A2,0 653 224.

[0003] It is also previously known that the amplitude of the QRS complex of ordinary surface ecg:s is varying with the respiration of the patient, see e.g. US 4,757,815.

[0004] It has now been found that the waveform or morphology of IEGM:s is varying with the respiration of the patient, and the present invention is based on this discovery.

Summary of the invention

[0005] The purpose of the invention is consequently to propose a new technique for detecting the respiration of a patient and use the results for controlling an implantable heart stimulator.

[0006] This purpose is obtained by a heart stimulator of the kind defined in the introductory portion of the specification and having the characterizing features of claim 1.

[0007] Thus the beat-to-beat variability in the IEGM signal morphology is utilised to extract respiration related parameters, while slow morphology variability extending over several cardiac cycles and related to the workload is filtered away. The heart stimulator according to the invention is consequently based merely on IEGM signal processing for realizing an accurate respiration sensor, eliminating the need for mechanical sensor components. Furthermore the technique can be easily implemented in current devices.

[0008] According to an advantageous embodiment of a heart stimulator according to the invention, said classifier means comprises a neural network clustering stored IEGM signals into a predetermined number of classes depending on their waveforms. By using a neural network the classification technique used is self-organizing and adaptive and can be implemented in existing devices. The neural network realises a self-organizing feature map, which can be trained to cluster the data into a predetermined number of classes.

[0009] According to another advantageous embodiment of the stimulator according to the invention, said respiration related parameters are respiration rate and respiration depth. From these two parameters the minute ventilation can be determined and used for controlling the heart stimulator.

[0010] According to still another embodiment of the heart stimulator according to the invention a second filtering means is connected in parallel to said first filtering means to extract a parameter related to the workload for the patient from slow variability, extending over several cardiac cycles, in IEGM signal classification while filtering away beat-to-beat classification variability and in that said control means is adapted to receive said workload related parameter to control the delivery of stimulation pulses from said pulse generator depending on said parameter. In this way a workload and respiration dual sensor is obtained which can be used for the control of a heart stimulator. Such a dual sensor will thus extract two different control quantities, i.e. workload and respiration, from the IEGM signal.

[0011] According to yet another advantageous embodiment of a heart stimulator according to the invention, said first and said second filtering means comprise high pass and low pass filters respectively. In this way respiration and workload parameters can be concurrently extracted from fast, beat-to-beat variability of the classification of IEGM signals and slow variability, extending over several cardiac cycles, of said classification respectively.

Brief description of the drawings

[0012] The invention will now be explained in great

detail with reference to the accompanying drawings, on which:

Figure 1 is a diagram showing 60 recordings of IEGM signals from 60 paced cardiac cycles,

Figure 2 is a diagram showing on a larger scale a portion of the IEGM:s shown in figure 1 corresponding to the ST-T segment of the ordinary surface ecg,

Figure 3 is a diagram showing the two end maps and the midpoint map obtained by applying a self-organizing feature map (SOFM) algorithm to the signals in figure 2,

Figure 4 shows the time evolution of the classification output obtained from the SOFM and the time evolution of the signal from a fast thermistor positioned in one nostril of a patient when recording the IEGM:s,

Figure 5 s a schematic block diagram of an embodiment of an implantable heart stimulator according to the invention,

Figure 6 is a diagram illustrating principally the variation in classification of IEGM:s recorded for different workloads, and

Figure 7 is a block-diagram showing the basic structure of a respiration and workload dual sensor of the heart stimulator according to the invention.

Description of preferred embodiments

[0013] Figure 1 shows 60 IEGM:s recorded by a bipolar lead from a patient paced at a fixed heart rate of 70 bpm. The lead was positioned in the ventricle and both sampling and stimulation was performed via the same lead in the same way as described in the above-mentioned US 5,782,885. The patient was resting.

[0014] During these measurements the temperature of the patients expiration air at one nostril was measured by a fast reacting thermistor to directly monitor the respiration of the patient and get an estimate of both respiration rate and depth, cf. figure 4.

[0015] A self-organizing feature map (SOFM) was applied to a window of about 100 ms of the recorded IEGM substantially corresponding to the ST-T segment of corresponding surface ecg:s, delimited by the vertical lines a and b in figure 1 and shown in a larger scale in figure 2. The SOFM algorithm used in this example had 11 input nodes and 10 output nodes. Each input node corresponds to an amplitude sample in the ST-T segment, i. e. a sampling rate of 100 samples/s. The output nodes correspond to different morphological classification of the input signal, cf. also the technique described in the above-mentioned US 5,782,885.

[0016] The SOFM algorithm converges to a low mean error that is a prerequisite for accurate map formation. In figure 3 the two end-maps and the midpoint map (curve B) obtained from the data of figure 2 are plotted, curve A and curve C being the respective end-maps. Figure 3 shows the existence of a valid topological relation between the morphology represented by the different output nodes from the SOFM.

[0017] When the recorded 60 IEGM:s were classified by the SFOM algorithm it was found that the classification varied with the number of the heart beat as shown in the trace c in figure 4. Trace d in figure 4 shows the corresponding curve obtained from the signals from a fast thermistor positioned in one nostril of the patient. From figure 4 it is obvious that traces c and d are correlated, i.e. the IEGM SOFM output is related to the respiration.

[0018] The respiration rate is directly deductible from figure 4, however, figure 4 also comprises information about respiration depth, see e.g. the trend indicated by the slanted line during the first 10 cardiac cycles. By forming the product of a number of zero-crossings and the average peak amplitude during a specified period of time of trace c in figure 4 a quantity is obtained which correspond to the minute ventilation. Thus with the present invention it is possible to obtain a quantity corresponding to the minute ventilation for use in controlling the pulse generator. Of course obtained values of the respiration rate can be directly used in the control of the heart stimulator, if appropriate.

[0019] By using a SOFM technique as described above the set-up of the sensor is obtained automatically and it will be adapted, i.e. it may track long-term alterations of the IEGM. The number of classes can be adapted to measured data. If these data comprise a plurality of classes representing different phases of the respiratory cycle, the SOFM may be trained to cluster the data into e.g. 20 classes, each class relating to a specific phase of the respiratory cycle. Subsequent unknown IEGM signals will then be classified into one of these 20 classes.

[0020] Since the morphology is changed somewhat when the stimulation rate is changed, a workload-stimulation rate matrix in analogy to what is disclosed in the above-mentioned US 5,782,885 is needed. Alternatively, a 2-dimensional feature map can be used.

[0021] For the SOFM a neural network of the kind described in the mentioned US 5,782,885 is preferably used for clustering IEGM signals into a predetermined number of classes based on morphological similarities.

[0022] Figure 5 shows an embodiment of the implantable heart stimulator according to the invention. Connected to the input terminals 1 and 2 of the unipolar or bipolar lead is a pulse generator 3, shown as a functional block. This block contains circuitry for generating the stimulation pulses. The block also contains circuitry for interfacing with the control unit 4, which is controlling the delivery of stimulation pulses from the pulse generator.

[0023] The heart stimulator also includes an IEGM amplifier 5 for amplification and filtering of the IEGM signal. The amplifier 5 is connected to the input terminals

for receiving IEGM signals from connectable implanted leads and for amplifying IEGM signals.

[0024] The signals from the amplifier 5 are supplied to a classifier 6. Its function is to classify the recorded IEGM:s into different morphological groups or classes. The classifying function can be implemented in several different ways both with regard to the underlying algorithms and the hardware used, cf. the above-mentioned US 5,782,885.

[0025] A memory means 13 is provided for storing signal waveforms from a plurality of received IEGM signals and the classifier is adapted to classify a current IEGM signal by matching its waveform to one of said stored signal waveforms, by using e.g. pattern recognition algorithms. As explained above the classifier preferably comprises a neural network clustering stored IEGM signals into predetermined number of classes depending of their waveforms. IEGM signals supplied to the neural network are then encoded and stored in said memory means 13 in encoded formed for subsequent classification use.

[0026] The control unit 4 interprets the classification results from the classifier 6 and based thereon senses control signals to a control input 10 of the pulse generator 3.

[0027] Figure 6 illustrates qualitatively the variation of the classification obtained by the above described technique as a function of time for different workload levels, viz. rest, 30 W and 50 W. As appears from this figure a changed workload results in a change of the IEGM classification. On this slow, workload-depending variability of the classification a faster, beat-to-beat variability is superposed. This beat-to-beat variability is caused by the respiration as described above. These two kinds of IEGM classification variability make design of a respiration and workload dual sensor possible based exclusively on IEGM signal processing.

[0028] Figure 7 shows the structure of such a dual sensor, which can be implemented in the heart stimulator according to the invention. Thus recorded IEGM:s are classified in a classifier 11 by using a SOFM algorithm, preferably in the form of a neural network. The output signal from the classifier 11 is supplied to a high pass filter 12 and a low pass filter 14 connected in parallel. The high pass filter 12 is adapted to extract parameters related to the patient's respiration from beat-to-beat variability in the IEGM classification while filtering away slow classification variability extending over several cardiac cycles, whereas the low pass filter 14 is adapted to extract the parameter related to workload for the patient from the slow variability, while filtering away beat-to-beat variability. The resulting respiration related and workload related parameters are respectively supplied to a signal fusion unit 16 which generates an output signal depending on the values of these supplied parameters which output signal is used as a control signal for the pulse generator.

[0029] The signal fusion unit 16 can be realised in many different ways, e.g. in analogy with known, so called MV-activity combined sensors. Such a sensor combines a minute volume (MV) sensor with a workload activity sensor. In this known sensors the minute volume is determined from measurements of the impedance across the patient's thorax by means of electric current pulses. Since the impedance varies during the respiration cycle the minute volume can be estimated in this way. As a workload sensor an accelerometer is used which determines the movement of the patient's body. The minute volume signal and the workload signal are then combined, preferably by using so-called fuzzy logic means for controlling the stimulation rate of a pacemaker.

[0030] Above, the invention is described in connection with a state of complete stimulation, i.e. each heart beat is a stimulated heart beat. The technique according to the invention can, however, also be used in a state of spontaneous heart activity of the patient. For patients suffering form e.g. chronotropic incompetence, i.e. the heart exhibits spontaneous activity but the heart rate is not increasing sufficiently in case of increasing workload of the patient, a heart stimulator according to the invention could be an useful aid.

Claims

1. An implantable heart stimulator comprising a pulse generator (3) for delivering stimulation pulses to the heart of a patient, an IEGM means (5) for registering electric signals associated with the patient's heart, a classifier means (6,11) for classifying the received electric IEGM signals according to their waveforms in at least one segment of the cardiac cycle, and a control means (4) for controlling said pulse generator depending on the classification of said IEGM signals, **characterized in that** a first filtering means (12) is provided to extract parameters related to the patient's respiration from beat-to-beat variability in the IEGM signal classification while filtering away slow classification variability extending over several cardiac cycles, and **in that** said control means (4) is adapted to receive said respiration related parameters to control the delivery of stimulation pulses from said pulse generator (3) depending on said parameters.

2. The heart stimulator according to claim 1, **characterized in that** a memory means (13) is provided for storing signal waveforms from a plurality of received IEGM signals.

3. The heart stimulator according to claim 2, **characterized in that** said classifier means (11) is adapted to classify a current IEGM signal by matching its waveform to one of said stored signal waveforms.

4. The heart stimulator according to claim 3, **characterized in that** said classifier means (6, 11) is adapted to use pattern recognition algorithms for the waveform matching.

5. The heart stimulator according to claim 2, **characterized in that** said classifier means (6, 11) comprises a neural network clustering stored IEGM signals into a predetermined number of classes depending on their waveforms.

6. The heart stimulator according to any of the claims 2 - 5, **characterized in that** said neural network is adapted to receive said plurality of IEGM signals and encode their respective waveforms and **in that** said memory means (13) is provided to store said IEGM signal waveforms in encoded form.

7. The heart stimulator according to any of the preceding claims, **characterized in that** said classifier means (6, 11) is adapted to classify IEGM signals according to their waveforms in signal segments corresponding to the ST interval of ordinary ecg:s.

8. The heart stimulator according to claim 7, **characterized in that** the length of said signal segment is of the order of 100 msec.

9. The heart stimulator according to any of the claims 1 - 6, **characterized in that** said classifier means (6,11) is adapted to classify IEGM signals according to their waveforms in signal segments corresponding to the T-wave of ordinary ecg:s.

10. The heart stimulator according to any of the preceding claims, **characterized in that** said respiration related parameters are respiration rate and respiration depth.

11. The heart stimulator according to any of the preceding claims, **characterized in that** a second filtering means (14) is connected in parallel to said first filtering means (12) to extract a parameter related to the workload for the patient from slow variability, extending over several cardiac cycles, in IEGM signal classification while filtering away beat-to-beat classification variability, and **in that** said control means (4) is adapted to receive said workload related parameter to control the delivery of stimulation pulses from said pulse generator (3) depending on said parameter.

12. The heart stimulator according to claim 11, **characterized in that** said first and said second filtering means (12, 14) comprise high-pass and low-pass filters respectively.

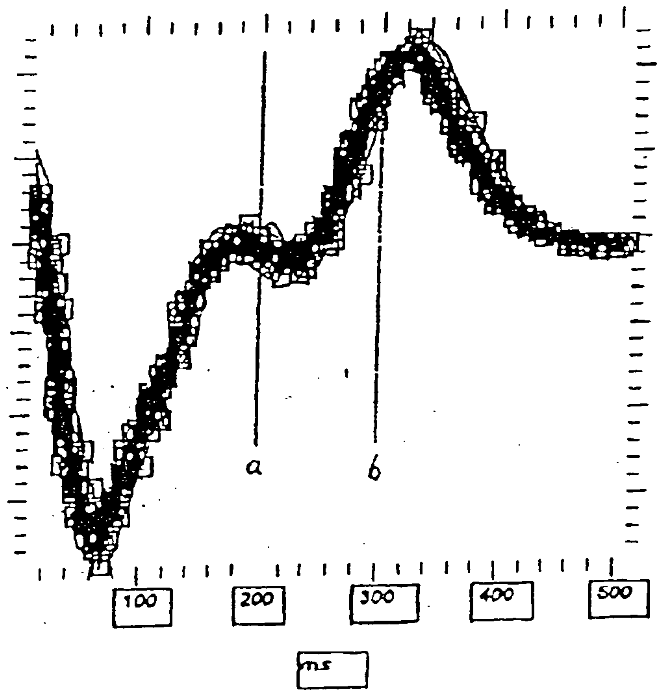

Fig. 1

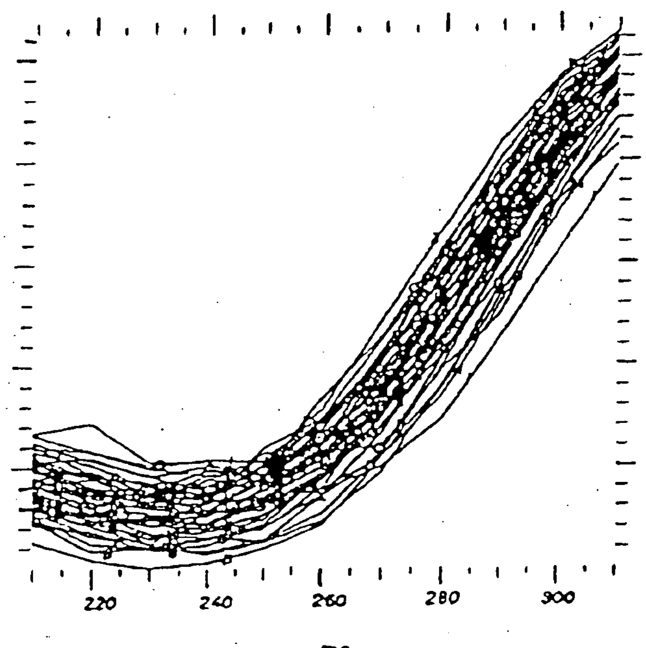

Fig. 2

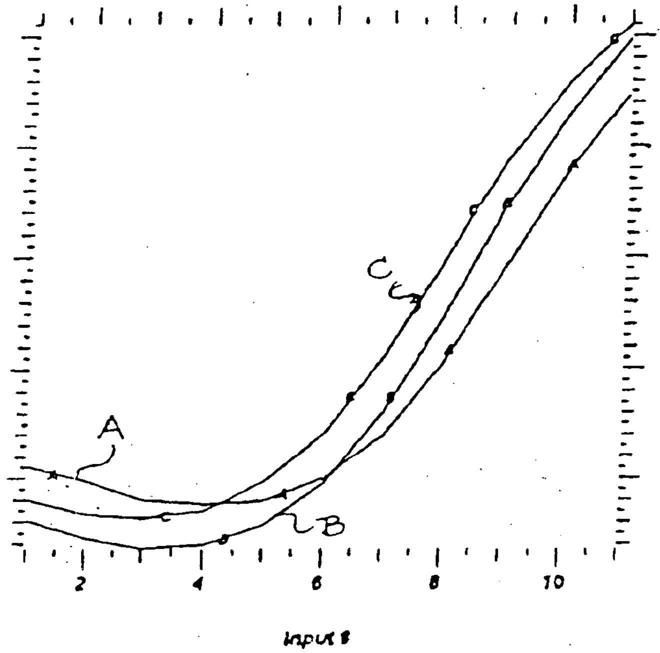

Fig. 3

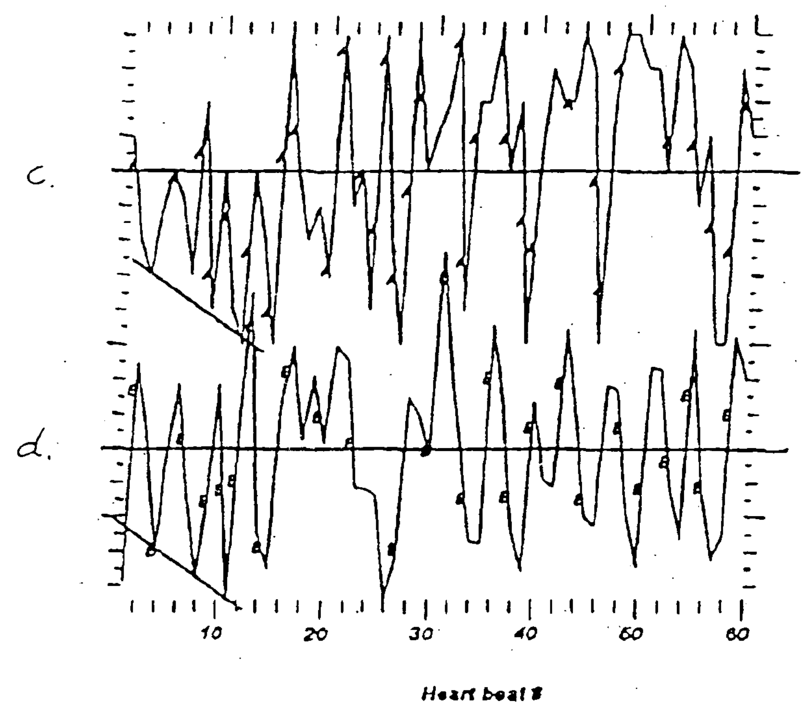

Fig. 4

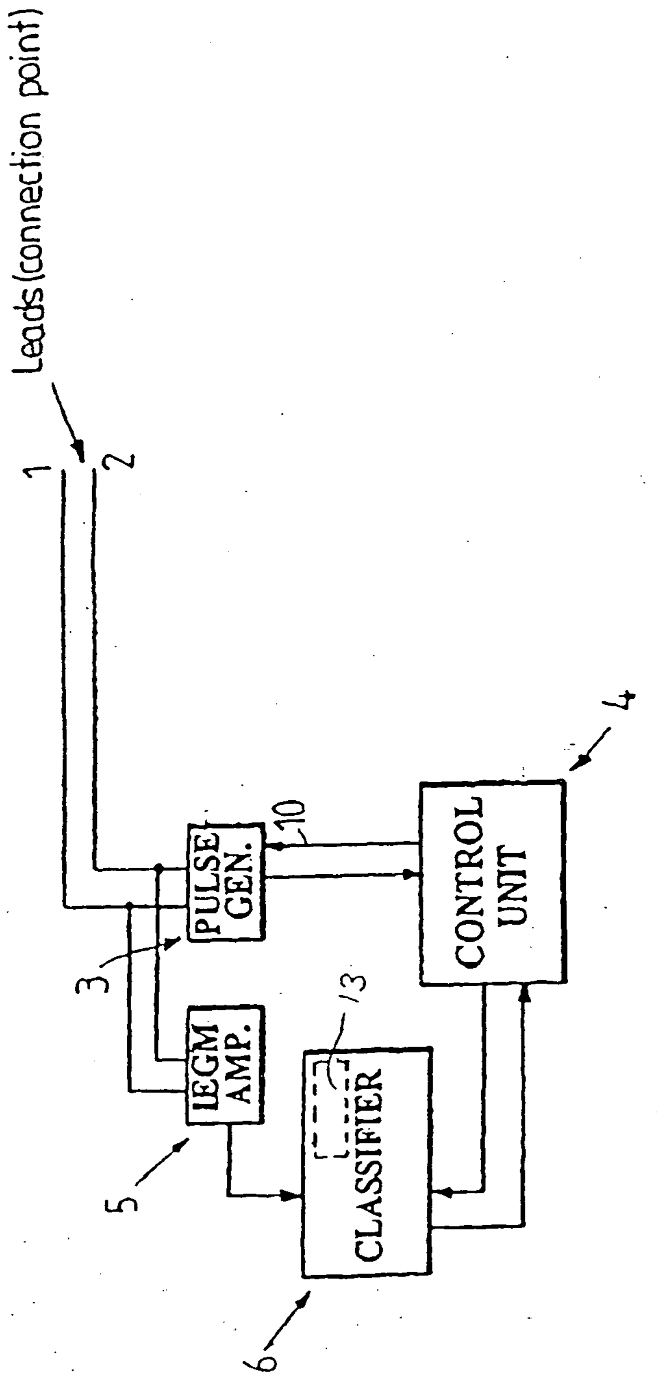
Leads(connection point)
1
2
PULSE GEN.
10
3
CONTROL UNIT
4
IEGM AMP.
5
CLASSIFIER
13
6

Fig. 5

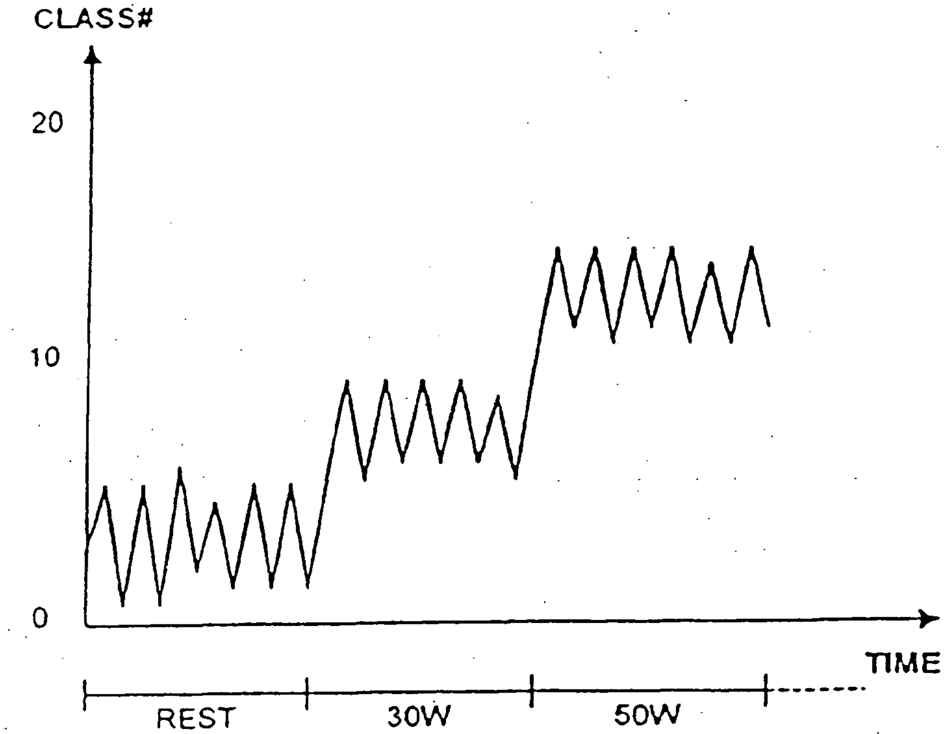
CLASS#
20
10
0
TIME
REST
30W
50W

Fig. 6

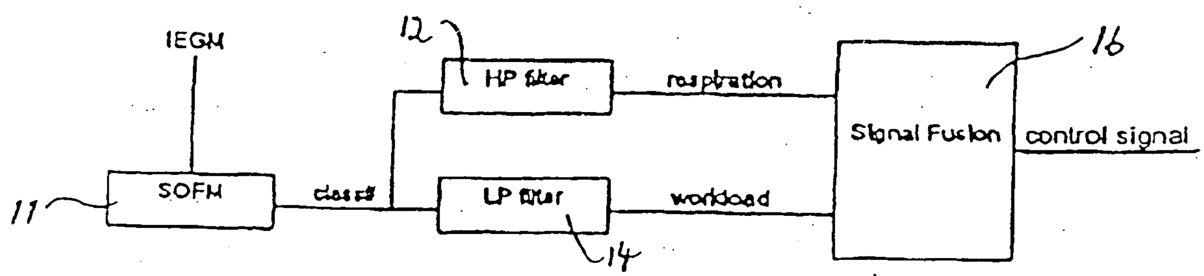
IEGM
12
HP filter
respiration
16
Signal Fusion
control signal
11
SOFM
class#
LP filter
workload
14

Fig. 7